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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,304	08/21/2003	Samuel I. Stupp	126481.01001	8011
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BENET GROUP LLC C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER CORDERO GARCIA, MARCELA M	
			ART UNIT 1654	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/645,304

Applicant(s)

STUPP ET AL.

Examiner

Marcela M. Cordero Garcia

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 22-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/07 and 04/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 29, 2007 has been entered.

Claims 1-24 are pending. Claims 22-24 are withdrawn as not drawn to the elected group. Claims 1-21 are presented for examination on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

### Written Description

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

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"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

***In the instant case, the claims are drawn to a peptide amphiphile composition comprising: a hydrophobic component having a single alkyl chain; and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a non-***

**spherical micelle.** The generic peptide amphiphiles with the limitations "hydrophobic component", "hydrophilic component", "formation of non-spherical micelle" (e.g., claim 1) and "structural peptide" and "functional peptide" (e.g., claim 9) have not been provided with ample written description, i.e., a representative number of compounds and guidance encompassing those limitations needs to be provided given the fact that the instant invention is not drawn to a core nuclear structural feature. Rather, the peptide amphiphile composition is described using functional language such as an amphiphile that self aggregates as a 'non-spherical micelle' and utilizing very generic structural language, such as 'having a net charge at physiological pH'. Under the written description requirement, the specification must provide description of a compound with a known or disclosed correlation between structure and function. The disclosure teaches that "similar amphiphile molecules can also be designed to provide micelles having structural shapes that may differ from a fiber like appearance such as but not limited to spheres" (e.g., page 17, [0042]) and that cylindrical (fiber like) micelles are formed because of the amphiphiles overall conical shape (e.g., [0042]). The MPEP states "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed." See MPEP 2163. The claims do not provide a precise definition, such as by structural formula, chemical name, or physical properties to provide support for the claimed chemical invention. Furthermore, the art does not define a strong correlation between structures and function that one of ordinary skill in the art would be able to predict, with a reasonable degree of confidence, the structure of the claimed invention from a recitation of its function. For example, Applicant admits that the art cited by examiner, i.e., Forns et al., teaches a peptide amphiphile having an alkyl (hydrophobic component) and a peptide

(hydrophilic component) forming  $C_{12}$ -(Gly-Pro-Hyp)<sub>3</sub>-[Gly-Val-Lys-Gly-Asp-Lys-Gly-Asn-Pro-Gly-Trp-Pro-Gly-Ala-Pro-(Gly-Pro-Hyp)<sub>4</sub>-NH<sub>2</sub>], and inherently has a positive net charge at physiological pH (see Office Action of June 27, 2006, pages 3-4), thereby meeting the limitations of claim 1, does not necessarily form micelles (see, Applicant's response of September 27, 2006, page 10, lines 5-15). Therefore, even though the compound of Forns et al. anticipates the structural limitations claimed, it does not possess the functional properties instantly claimed. However, the disclosure does not shed any light for one of ordinary skill in the art (such as a common molecular core) to find the peptide amphiphiles instantly claimed. In other words, there is no sufficient guidance within the disclosure for one of ordinary skill in the art to find such peptide amphiphiles, because, although the specification does provide examples of what qualify as compounds of the claimed invention [e.g., to Table 1 (SEQ IDs 1-22) and Figures 1-2] these are limited to a few examples of peptide amphiphiles which form only cylindrical (nanofiber-like) micelles, which do not adequately represent the breadth of the instant claims.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of polypeptide with an alkyl tail forming any kind of structural three-dimensional shape other than spherical. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite

some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is limited to a few examples, e.g., to Table 1 (SEQ IDs 1-22), and Figures 1-2 describing cylindrical (nanofiber-like) micelles in contrast with the broadly claimed peptide amphiphiles comprising structural peptides, functional peptides and alkyl groups (see, pages 3-5) and then forming non-spherical micelles. In addition, with respect to the alkyl group, see, page 10, [0031], that the alkyl tail must be greater than C<sub>6</sub> in length. However, the specification lacks sufficient variety of species to reflect this variance in the genus, as only a few peptides and C<sub>16</sub> are exemplified (e.g., page 14). The specification does not provide any guidance for alkyl chains that may comprise spacers or heteroatoms within the backbone and/or any other discontinuity and does not provide a limiting definition for 'alkyl group' or for 'single alkyl group'. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.



### **New Matter**

The claims have been amended (cf. amendment filed September 27, 2006) to recite the limitation "self assembling to form a non-spherical micelle". However, the term non-spherical is deemed to constitute new matter.

### **Lack of Ipsis Verbis Support**

The specification is void of any support that would clearly indicate that non-spherical micelles in general, encompassing as such a wide variety of 3D shapes of micelles, are instantly disclosed. The disclosure teaches that cylindrical (nanofiber like) micelles are formed because of the amphiphiles overall conical shape (e.g., Figures 1-2, [0042]) and that "similar amphiphile molecules can also be designed to provide micelles having structural shapes that may differ from a fiber like appearance such as but not limited to spheres" (e.g., page 17, [0042]). This reference does not provide literal support for the limitation "non-spherical micelle".

### **Lack of Inherent Support**

"While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." See MPEP 2163. Based on the examples in the Figures (See Figures 1-11), the type of non-spherical micelles disclosed appears to be limited to nanofiber like (cylindrical) micelles. Thus, one cannot readily conclude, based on the examples alone, that there is support

for the broad term "non-spherical micelles" but rather only for cylindrical, nanofiber like micelles. Accordingly, the new limitation constitutes new matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***Claim 9 is drawn to a peptide-amphiphile compound comprising: an alkyl tail, a structural peptide covalently bonded to said alkyl tail; and a functional peptide covalently bonded to said structural peptide opposite said alkyl tail; said function peptide having an overall conical shape and a net charge at physiological pH.*** Claim 9 is rendered vague and indefinite by the phrases "structural peptide", "functional peptide" and "overall conical shape" because the metes and bounds for such terms are not well delineated, i.e., what would constitute a "structural peptide" versus a "functional peptide" and what structural attributes one would consider in order to determine whether a peptide is "structural" or "functional" or both or neither, or, additionally, what is an "overall conical shape" and how does one go about determining the "overall shape" of a molecule, i.e., under which physical-chemical conditions and based on what parameters one would determine that a shape is conical.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 6, 7, 9, 11, 14-15, 17, 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Stupp et al. (US 6,890,654, citation C in the PTO-892 of 11/15/05).

Stupp et al. teach a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group; and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH said peptide amphiphile self-assembling to form a cylindrical (non-spherical) micelle [see, e.g., Figure 4 and column 9, lines 40-67].

The limitations of claims 3, 6, 11, 14 and 19 are inherent to the composition taught by Stupp et al. (see Figure 4) because the peptide-amphiphile of Stupp et al. contains a phosphorylated serine (-1), two carboxyl groups (-2) and one arginine (+1), therefore its net charge at physiological pH is -2. In addition, the limitations of claims 7 and 15 are deemed inherent since the peptide component (e.g., structural peptide)

therein comprises, for example, hydroxyl groups in the phosphorylated serine, which are capable of intermolecular covalent bond formation. The limitations of claims 20-21

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-2, 9-10, 14-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fields et al. (US 6,096,863, citation D in the PTO-892 of 11/15/05).

Fields et al. teach a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group; and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH said peptide amphiphile self-assembling to form a non-spherical micelle (see, e.g., claims 1-16, especially claims 7, 11). The limitation "non-spherical" micelle is taught, e.g., at column 7, lines 6-16. The limitation of claims 2, 6, 18 is inherent to the composition taught by Fields et al. because the peptide-amphiphile of column 3, lines 1-19, wherein the peptide is the  $\alpha 1(IV)1263-1277$ , has a net positive charge (see also, e.g., claims 7 and 11 of Fields et al.). Please note that the species taught by Fields et al. reads upon a "single alkyl chain" and "alkyl tail" because the instant disclosure does not limit the terms to alkyl chains comprising only carbons. The limitations of claims 6-7, 14-15 are inherent to the structure of the peptide, because the peptide amphiphile contains functional moieties capable of intermolecular covalent bond such as Asp (e.g., column 14, lines 55-59). Please note that a hairpin structure reads upon the limitation of claim 9, i.e., "overall conical" (see e.g., claim 16). Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1, 3, 4, 5, 7, 17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (Chem Letters, 1984, cited in the PTO-892 of 6/27/06).

Yamada et al. teach a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group; and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH said peptide amphiphile self-assembling to form, e.g., a tubular and helical micelles in water (e.g., Figure 2) non-spherical micelle (see, e.g., Compound 2,  $2C_{12}Glu_{14}$ , Figures 1-2, pages 1714-1715). Please note that the species taught by Fields et al. reads upon a "single alkyl chain" and "alkyl tail" because the instant disclosure does not limit the terms to alkyl chains comprising only carbons.

The limitations of claims 3, 4, 5 are taught in Figure 1, because, e.g.,  $2C_{12}Glu_{14}$  comprises 14 negative charges, therefore its net charge at physiological pH is -14. In addition, the limitation of claim 7 is deemed inherent since the peptide component (e.g., structural peptide) therein comprises, for example, hydroxyl groups in the glutamic acid portion, which are capable of intermolecular covalent bond formation. The limitations of claims 19-21 are taught, e.g., at page 1715, lines 11-18. Therefore, the reference is deemed to anticipate the instant claims above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 9-13, 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 6,890,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are drawn to a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a non-spherical micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the claimed composition of US '654.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of

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compending Application No. 10/294,114. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are drawn to a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, wherein the peptide amphiphile compound self-assembles to form a non-spherical micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the claimed composition of Application '114.

This is a provisional obviousness-type double patenting rejection.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, 10-14 and 16 of compending Application No. 10/368,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are drawn to a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a non-spherical micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the claimed composition of Application '517.

This is a provisional obviousness-type double patenting rejection.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/534,266. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are drawn to a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group and a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH, said peptide amphiphile self assembling to form a non-spherical micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the claimed composition of US '266.

This is a provisional obviousness-type double patenting rejection.

### ***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcela M Cordero Garcia, PhD  
Patent Examiner  
Art Unit 1654

MMCG 04/07

4/30/07  
**ANISH GUPTA**  
**PRIMARY EXAMINER**